§ 225.158 Laboratory assays.

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

§ 225.165 Equipment cleanout procedures.

Adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

Subpart H—Labeling

§ 225.180 Labeling.

Labels shall be received, handled, and stored in a manner that prevents label mixups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used.

[51 FR 7390, Mar. 3, 1986]

Subpart I—Records

§ 225.202 Formula, production, and distribution records.

Records shall be maintained identifying the formulation, date of mixing, and if not for own use, date of shipment. The records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Such records shall be retained on the premises for 1 year following the date of last distribution.

(Approved by the Office of Management and Budget under control number 0910-0152)

[51 FR 7390, Mar. 3, 1986]

PART 226—CURRENT GOOD MAN-UFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

Subpart A—General Provisions

Sec.

 ${\tt 226.1} \quad {\tt Current\ good\ manufacturing\ practice}.$

226.10 Personnel.

Subpart B—Construction and Maintenance of Facilities and Equipment

226.20 Buildings.

226.30 Equipment.

Subpart C—Product Quality Control

226.40 Production and control procedures.

226.42 Components.

226.58 Laboratory controls.

Subpart D—Packaging and Labeling

226.80 Packaging and labeling.

Subpart E—Records and Reports

226.102 Master-formula and batch-production records.

226.110 Distribution records.

226.115 Complaint files.

AUTHORITY: 21 U.S.C. 351, 352, 360b, 371, 374.

Source: 40 FR 14031, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 226.1 Current good manufacturing practice.

(a) The criteria in §§ 226.10 through 226.115, inclusive, shall apply in determining whether the methods used in, or the facilities and controls used for the manufacture, processing, packing, or holding of a Type A medicated article(s) conform to or are operated or administered in conformity with current good manufacturing practice to assure that a Type A medicated article(s) meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this part 226 permit the use of precision, automatic, mechanical, or electronic equipment in the production of a Type A medicated article(s) when adequate inspection